REMARKS

The present response amends the specification and claims 1, 5, 7-11, 13, 28, 29, 31 and 34. In addition, claim 6 has been canceled without prejudice or disclaimer as to the subject matter recited therein. Therefore, claims 1-5, 7-13, and 28-37 remain pending in the captioned case. Further examination and reconsideration of the presently claimed application are respectfully requested.

Objections to the Claims

An objection was lodged against claim 13 for an informality. In response thereto, claim 13 has been amended to correct the dependency. Accordingly, Applicants believe this objection has been obviated in its entirety.

Section 102 Rejection

Claims 1, 2, 5-12 and 28-37 were rejected under 35 U.S.C. §102(b) as being anticipated by the U.S. Patent No. 5,976,110 to Greengrass et al. (hereinafter "Greengrass"). The standard for "anticipation" is one of fairly strict identity. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art of reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP 2131. Furthermore, anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, as arranged in the claim. *W.L. Gore & Assocs. V. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Using these standards, Applicants submit the cited art fails to disclose each and every element of the currently pending claims, some distinctive features of which are set forth in more detail below.

Greengrass fails to anticipate a catheter introducer including: (i) a cap portion in rotational securement with a distal end of the catheter introducer, and (ii) an elastic tube, which is arranged about a rotational axis of the catheter introducer and fixedly attached to both the cap portion and the distal end of the catheter introducer. Amended independent claim 1 recites, "wherein the proximal end of the catheter introducer comprises: a cap portion in rotational securement with the distal end of the catheter introducer; and an elastic tube arranged about a rotational axis of the catheter introducer and fixedly attached to the cap

portion and to the distal end of the catheter introducer..." Support for the amendments made to claim 1 may be found in originally filed claim 28 and claim 6 (now canceled), which further recites, "wherein rotation of the cap portion relative to the distal end of the catheter introducer modifies an internal diameter of the elastic tube."

Greengrass discloses a catheter introducer or "multi-purpose connector" (16) having a distal end (16A), a proximal end (16B) and a middle aperture (A). *See*, FIG. 1 of Greengrass. In addition, Greengrass teaches, "proximal end 16B is adapted to selectively close multi-purpose connector 16 to prevent leakage of fluid out of multi-purpose connector 16." (*see*, Greengrass, column 5, lines 5-10). However, Greengrass fails to teach or suggest that the proximal end (16B) of the multi-purpose connector (16) may include a cap portion and elastic tube, as recited in present claims 1 and 28.

Statements in the Office Action suggest that the proximal end (16B) of multi-purpose connector (16) may be interpreted to read upon the presently claimed "cap portion," and that an elastic tube is somehow arranged "inside" of proximal end 16B. The Examiner further suggests that "rotation of the cap portion relative to the distal end of the introducer modifies an internal diameter of the tube to seal the orifice… against leakage when the catheter is or is not inserted in the introducer (column 5, lines 5-10, 45-46 and column 6, lines 20-27). *See*, Office Action, page 3. The Applicants disagree for at least the reasons set forth in more detail below.

In the cited passages, Greengrass states, "proximal end 16B is adapted to selectively close multi-purpose connector 16 to prevent leakage of fluid out of multi-purpose connector 16." (*see*, Greengrass, column 5, lines 5-10). More specifically, Greengrass states that the proximal end 16B of multi-purpose connector 16 may be twisted shut "so that the aperture at the terminus of [proximal] end 16B used for insertion of epidural catheter 20 does not allow local anesthesia LA to leak back out of it." (*see*, Greengrass, column 5, lines 45-46 and column 6, lines 20-27). In light of such teaching, the Examiner concludes that the proximal end (16B) of multi-purpose connector (16) must include a cap portion and elastic tube, as presently claimed. This is an incorrect assumption.

First of all, the Examiner merely assumes that an elastic tube is included within or "inside" proximal end 16B. Such a tube is neither shown in the drawings nor described within the text provided by Greengrass. In other words, Greengrass fails to explicitly describe the presently claimed elastic tube as a necessary component of multi-purpose connector 16.

In addition, the presently claimed elastic tube cannot be considered to be an inherent feature of the multi-purpose connector described by Greengrass. For example, the elastic tube is described in the present claims as "arranged about a rotational axis of the catheter introducer and fixedly attached to the cap portion and to the distal end of the catheter introducer." If one were to (incorrectly) assume that an elastic tube was somehow included within multi-purpose connector 16, the elastic tube would have to: (i) be arranged about a rotational axis of multi-purpose connector 16, and (ii) be fixedly attached to the proximal end 16B (the so-called "cap portion") and to the distal end 16A of the connector. This means that the elastic tube would have to extend along a length of multi-purpose connector 16 between at least a lower portion of proximal end 16B (i.e., where proximal end 16B meets middle aperture A) and an upper portion of distal end 16A (i.e., where distal end 16A meets middle aperture A).

However, if the elastic tube were to extend between proximal end 16B and distal end 16A as explained, a user would not be able to administer or withdraw fluids through the middle aperture A, flexible tubing 18 and syringe S of Greengrass. In other words, an elastic tube arranged about a rotational axis of multi-purpose connector 16, and fixedly attached to proximal end 16B and distal end 16A would interfere with (if not completely block) fluid passage between tubing 18, middle aperture A and distal end 16A. As a result, the catheter system (10) of Greengrass would cease to function as intended.

The present invention overcomes this problem by arranging the side port (or "middle aperture") 824 within the distal end 826, and below the cap portion 822A and elastic tube 822C, of catheter introducer 820, as shown in FIGS. 8A-B. This configuration allows the elastic tube 822C to be arranged and attached, as claimed, without interfering with fluid passage into or out of the side port 824. The catheter introducer described in the presently claimed case is altogether different from Greengrass' connector, where the middle aperture A is arranged between the distal end 16A and proximal end 16B of multi-purpose connector 16. Unlike the presently claimed case, Greengrass' connector (16) does not allow an elastic tube to be arranged between the distal and proximal ends of the connector without compromising the intended functionality of the device.

As set forth above, Greengrass fails to either expressly or inherently describe a cap portion and elastic tube, as recited in present claims 1 and 28. As a consequence, Greengrass fails to anticipate all limitations of claims 1 and 28.

In addition to the independent claims, Greengrass fails to anticipate many of the limitations set forth in the dependent claims. For example, and as described in more detail below, Greengrass fails to anticipate the limitations set forth in claims 5, 7, 8, 29 and 35.

With regard to claims 7, 8 and 29, Greengrass fails to anticipate wherein rotation of the cap portion relative to the distal end of the catheter introducer reduces an internal diameter of the elastic tube. As noted above, Greengrass fails to anticipate a catheter introducer comprising a cap portion and elastic tube, as set forth in present claims 1 and 28. In fact, arguments are provided above to explain how the catheter device of Greengrass would cease to function as intended, if the proximal end 16B of multi-purpose connector 16 were modified to include the presently claimed elastic tube. For at least these reasons, Greengrass cannot be relied upon to teach or suggest that rotation of proximal end 16B (i.e., the alleged "cap portion") relative to the distal end (16A) of multi-purpose connector 16 (i.e., the alleged "catheter introducer") somehow reduces an internal diameter of an elastic tube, which is simply not included within the catheter system of Greengrass.

With regard to claims 5 and 35, Greengrass fails to anticipate a catheter threading assist guide, which is permanently attached to a proximal end of the catheter introducer to facilitate threading of a catheter through the catheter introducer and the insulated needle. Amended dependent claim 5 recites: "The catheter system as recited in claim 1, wherein the proximal end of the catheter introducer comprises a catheter threading assist guide, which is permanently attached to the proximal end of the catheter introducer to facilitate threading of the catheter through the catheter introducer and the insulated needle." Support for the amendments made to claim 5 may be found, e.g., on page 7, line 21 to page 8, line 2 of the Specification. Dependent claim 35 states, "wherein the step of administering local anesthetic and the step of administering fluids are conducted without a need for removing components from the catheter system." As described in more detail below, these limitations are not anticipated by Greengrass.

Statements in the Office Action suggest that the proximal end (16B) of multi-purpose connector (16) may be interpreted to read upon the presently claimed catheter threading assist guide (*see*, Office Action, page 3). The Applicants disagree. Although not illustrated in the drawings, Greengrass specifically mentions the use of a catheter threading assist guide, which is separate and distinct from the multi-purpose connector (16). For example, when describing the method steps necessary for using catheter system (10), Greengrass states that the "pink plastic threading assist guide should be removed from the in-dwelling catheter" system after the insulated needle is inserted into the patient and the correct needle position has been verified (*see*, Greengrass, column 6, line 41 to column 7, line 15). Since Greengrass never once suggests that the proximal end (16B) of multi-purpose connector (16) could somehow be disconnected from other parts of the multi-purpose connector (i.e., from middle aperture A and distal end 16A), the proximal end (16B) of multi-purpose connector (16) cannot be interpreted to read upon the presently claimed "catheter threading assist guide".

Furthermore, Greengrass states that the actual threading assist guide (i.e., the pink plastic one) should be removed **before** the catheter is inserted through the hemostatic valve of the multi-purpose connector and **before** regional anesthesia is administered to the patient (*see*, Greengrass, column 7, lines 13-32). As such, Greengrass fails to anticipate a catheter threading assist guide, which is permanently attached to a proximal end of the catheter introducer to facilitate threading of a catheter through the catheter introducer and the insulated needle. Greengrass also fails to anticipate a method where the step of administering local anesthetic is conducted without removing components (such as the threading assist guide) from the catheter system. As a consequence, Greengrass fails to anticipate all limitations of present claims 5 and 35.

For at least the reasons stated above, Applicant asserts that independent claims 1 and 28, as well as claims dependent therefrom, are not anticipated by the cited art. Accordingly, Applicant respectfully requests removal of this rejection.

Section 103 Rejection

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Greengrass in view of U.S. Patent No. 5,405,334 to Roth et al. (hereinafter "Roth"). In addition, claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Greengrass in view of U.S. Patent No. 6,363,273 to Mastrorio et al. (hereinafter "Mastrorio"). To establish a *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP 2143.03. Obviousness cannot be established by combining or modifying the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion or incentive to do so. *In re Bond,* 910 F. 2d 81, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990). The cited art does not teach or suggest all limitations of the currently pending claims, some distinctive limitations of which are set forth in more detail below.

Roth and Mastrorio cannot be combined with Greengrass to provide teaching or suggestion for a catheter introducer including: (i) a cap portion in rotational securement with a distal end of the catheter introducer, and (ii) an elastic tube, which is arranged about a rotational axis of the catheter introducer and fixedly attached to both the cap portion and the distal end of the catheter introducer. As noted above, Greengrass fails to anticipate all limitations of independent claims 1 and 28 by failing to disclose a cap portion and elastic tube, as presently claimed. In addition, Greengrass cannot be modified to include the presently claimed cap portion and elastic tube, because doing so would interfere with the fluid passage necessary to administer or withdraw fluids (i.e., via tubing 18, middle aperture A and distal end 16A). As a result, Greengrass cannot be relied upon to render all limitations of independent claims 1 and 28 obvious.

Roth and Mastrorio are not cited for teaching the limitations of independents claim 1 and 28, but instead, are relied upon for allegedly disclosing certain features outlined in dependent claims 3, 4 and 13. Because these claims are dependent on independent claim 1, they necessarily include all of the limitations recited in that claim.

However, like Greengrass, Roth and Mastrorio fail to teach, suggest or provide motivation for a catheter introducer including: (i) a cap portion in rotational securement with a distal end of the catheter introducer, and (ii) an elastic tube, which is arranged about a rotational axis of the catheter introducer and fixedly attached to both the cap portion and the distal end of the catheter introducer,

as recited in present claim 1. Therefore, Applicant's assert that even if Roth and Mastrorio were combined with Greengrass (without sufficient motivation to do so), the combined teachings of the cited art would still fail to disclose all limitations recited in claims 1, 3, 4 and 13.

For at least the reasons set forth above, the cited art fails to teach or suggest, and cannot be combined or modified to teach or suggest all limitations of independent claim 1. Therefore, claim 1 and claims dependent therefrom are patentably distinct over the cited art. Accordingly, removal of this rejection is respectfully requested.

CONCLUSION

The present amendment and response is believed to be a complete response to the issues raised in the Office Action mailed December 15, 2005. In view of the remarks traversing the rejections, Applicants assert that pending claims 1-13 and 28-37 are in condition for allowance. If the Examiner has any questions, comments or suggestions, the undersigned attorney earnestly requests a telephone conference.

REQUEST FOR EXTENSION

Applicant respectfully petitions the Commissioner for a one month extension of time under 37 C.F.R. § 1.136 to respond to the Office Action mailed December 15, 2005, such extension allowing the undersigned until April 15, 2006 to respond.

The Commissioner is authorized to charge the required fee or credit any overpayment to Daffer McDaniel, LLP Deposit Account No. 50-3268/5871-00101.

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